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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/774,021	02/06/2004	Orn Adalsteinsson	ARK-153US1	7718

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EXAMINER	
CHEN, STACY BROWN	
ART UNIT	PAPER NUMBER
1648	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	12/26/2006	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/774,021	ADALSTEINSSON ET AL.	
	Examiner	Art Unit	
	Stacy B. Chen	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 October 2006*.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *46,47 and 49-59* is/are pending in the application.

4a) Of the above claim(s) *52-59* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *46,47 and 49-51* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *06 February 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on October 17, 2006 has been entered. Claims 46, 47 and 49-51 are under examination. Claims 52-59 remain withdrawn from consideration being drawn to non-elected subject matter.

Specification

(*New Objection*) The specification, as amended by the amendment filed October 17, 2006 is objected to under 35 U.S.C. 132(a) because it introduces new matter into the disclosure. 35 U.S.C. 132(a) states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: Page 11, paragraph beginning on line 8, "which is hereby incorporated by reference". An incorporation-by-reference statement added after the filing date of an application is not permitted because no new matter can be added to an application after its filing date.

Claim Rejections - 35 USC § 112

Claims 46, 47 and 49-51 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims remain rejected because of the indefiniteness of the term "active egg fraction" What component is the active fraction or the anti-inflammatory fraction? The examples show a whole egg, yet the "active" fraction and "anti-inflammatory fraction" is not identified. The metes and bounds of the "active egg fraction" cannot be determined without a definition.

Applicant's arguments regarding "active egg fraction" have been carefully considered but fail to persuade. Applicant argues that the active egg fraction comprises "supranormal levels of an anti-inflammatory composition". Applicant asserts that the specification defines the anti-inflammatory composition as "the composition disclosed in U.S. Serial Number 09/233,379 and here, which counteracts or suppresses the inflammatory process", page 11, lines 16-18. Applicant argues that the active egg fraction has been defined as that fraction of the egg that contains supranormal levels of an anti-inflammatory factor, wherein the terms "anti-inflammatory" and "supranormal levels" are clearly defined. These component parts of the active egg fraction are characteristics that distinguish the claimed active egg fraction from other potential fractions of an egg.

In response to Applicant's arguments, the active egg fraction remains indefinite. Although Applicant has in mind a characteristic of the active egg fraction (anti-inflammatory activity), that characteristic is not sufficient to distinguish it from the rest of the egg. Applicant has not provided a structure of the active egg fraction, and since Applicant's invention requires supranormal levels of the active egg fraction, one of skill in the art needs to know what the active egg fraction is comprised of. Further, one cannot know the metes and bounds of the claims without an understanding of what constitutes a supranormal level of an anti-inflammatory composition.

Applicant is attempting to incorporate a definition into the specification from U.S. Application 09/233,379. This incorporation by reference is not proper, as discussed above. Thus, 09/233,379 cannot be relied upon to define any terms in the instant specification and claims. Therefore, the rejection is maintained.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

(*New Rejection*) Claims 46, 47 and 49-51 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. To provide adequate written description and evidence of possession of a claimed genus, the specification must provide sufficient distinguishing identifying characteristics of the genus. The factors to be considered include disclosure of complete or partial structure, physical and/or chemical properties, functional characteristics, structure/function correlation, methods of making the claimed product, or any combination thereof.

The claims are drawn to a composition comprising glucosamine and an active egg fraction, wherein the active egg fraction further comprises supranormal levels of an anti-inflammatory composition. Applicant defines the anti-inflammatory composition as the

composition as "the composition disclosed in U.S. Serial Number 09/233,379 and here, which counteracts or suppresses the inflammatory process", page 11, lines 16-18. The only factor present in the claim is a function (anti-inflammatory). The specification improperly incorporates by reference the definition of the anti-inflammatory composition. Applicant has not adequately identified the anti-inflammatory composition.

An application as filed must be complete in itself in order to comply with 35 U.S.C. 112. An application for a patent when filed may incorporate "essential material" by reference to (1) a United States patent or (2) an allowed U.S. application, subject to the conditions set forth below. "Essential material" is defined as that which is necessary to (1) support the claims, or (2) for adequate disclosure of the invention (35 U.S.C. 112).

In this case, Applicant attempts to incorporate essential material from an unpublished U.S. patent application that is abandoned. Accordingly, in the absence of sufficient recitation of distinguishing identifying characteristics, the specification does not provide adequate written description of the claimed compositions comprising supranormal levels of an anti-inflammatory composition.

Claim Rejections - 35 USC § 102

Claim 46 remains rejected under 35 U.S.C. 102(b) as being anticipated by Kondo *et al.* (US 4,367,309, "Kondo"), for reasons of record. Claim 46 is drawn to a composition comprising glucosamine and an active egg fraction, wherein the active egg fraction further comprises supranormal levels of an anti-inflammatory composition. (The specification does not clearly define "active" egg fraction, nor "supranormal levels of an anti-inflammatory composition", so

the egg fraction is interpreted as any egg fraction with no specific activity required.) Kondo discloses a composition comprising a glycoprotein (conjugated protein) containing a carbohydrate. Specifically, the glycoprotein is egg albumin and the carbohydrate is glucosamine (column 2, lines 5-22). Therefore, lacking a clear definition of "active egg fraction", the claim remains anticipated by Kondo.

Applicant's argument has been considered, but fails to persuade. Applicant argues that Kondo fails to teach an active egg fraction that further comprises supranormal levels of an anti-inflammatory composition. In response to Applicant's argument, the definitions of the "active" egg fraction, and "supranormal levels of an anti-inflammatory composition" are not clearly or appropriately defined (improper incorporation by reference). Therefore, the claim remains rejected for reasons of record.

Claim Rejections - 35 USC § 103

The rejection of claims 46, 47 and 49-51 under 35 U.S.C. 103(a) as being unpatentable over Adalsteinsson *et al.* (WO 99/36077, "Adalsteinsson") in view of Yue (US 6,251,863), is maintained for reasons of record. The claims are drawn to a composition comprising glucosamine and an active egg fraction, wherein the active egg fraction further comprises supranormal levels of an anti-inflammatory composition. (The specification does not clearly define "active" egg fraction, nor "supranormal levels of an anti-inflammatory composition", so the egg fraction is interpreted as any egg fraction with no specific activity required.) The egg fraction is egg yolk. (The specification does not clearly define "anti-inflammatory fraction of the yolk", so the anti-inflammatory fraction is interpreted as any egg fraction of a yolk with anti-

inflammatory activity.) The glucosamine is glucosamine HCl or glucosamine sulfate, in the amount of approximately 10 mg to 5 grams. The immunogenic vaccine that is used to hyperimmunize the chicken from which the egg is taken, comprises various immunogens selected from a list in claim 51.

Adalsteinsson discloses a composition for preventing or reducing arthritis and/or autoimmune disease. Adalsteinsson discloses that there is activity in egg and egg products from hyperimunized avians that prevents or reduces arthritis and/or autoimmune diseases in mammals. The composition comprises an egg or fraction thereof, wherein the egg has been hyperimmunized with at least one antigen (abstract). The antigen is from bacteria, viruses, protozoa, fungi and cellular antigens (Adalsteinsson, claim 8). The composition also contains NSAIDs or DMARDs (claim 23). Adalsteinsson fails to teach glucosamine as part of the composition.

However, Yue teaches that glucosamine sulfate has been shown to treat joint disease. Yue suggests that it is a preferable treatment for the inflammation and pain of the joints instead of NSAIDS (col. 5, lines 19-26). It would have been obvious to substitute the glucosamine sulfate of Yue for Adalsteinsson's NSAIDs or DMARDs. One would have been motivated by Yue's teaching that glucosamine sulfate is a preferable treatment for inflammation instead of NSAIDs. One of ordinary skill in the art would have had a reasonable expectation of success that glucosamine would work in Adalsteinsson's method because Adalsteinsson uses an anti-inflammatory drug, and glucosamine is a known anti-inflammatory treatment, evidenced by Yue. Determining the dosages of glucosamine and egg would have been well within the ability of one

of ordinary skill. Therefore, the invention as a whole would have been prima facie obvious to one of ordinary skill in the art at the time of the invention.

Applicant's arguments have been fully considered but fail to persuade. Applicant's substantive arguments are primarily directed to the following:

- Applicant asserts that Adalsteinsson specifically teaches the use of the hyperimmune egg to protect the gastrointestinal tract from damage resulting from NSAIDs or DMARDs.
  - In response to Applicant's assertion, the Office acknowledges that Adalsteinsson discloses that NSAIDs or DMARDs can cause gastrointestinal tract damage (page 3, lines 14-20). The Office also acknowledges that Adalsteinsson's discovery is that the hyperimmunized egg imparts some anti-inflammatory benefit. However, the Office does agree with Applicant that Adalsteinsson suggests that the hyperimmunized egg product is used to protect against the effects of NSAIDs or DMARDs. Adalsteinsson's disclosure simply discloses that NSAIDs and DMARDs can cause gastrointestinal damage, and that the hyperimmunized egg product does not carry the same risks. Adalsteinsson does not teach that the hyperimmunized egg product somehow prevents NSAID or DMARD damage to the gastrointestinal tract. The two products act separately.
- Applicant argues that glucosamine is not known to cause gastrointestinal tract damage, and thus one would not have been motivated to use Adalsteinsson's hyperimmunized egg product to protect against gastrointestinal tract damage.
  - In response to Applicant's argument, the Office does not agree with Applicant's interpretation of Adalsteinsson. Adalsteinsson's hyperimmunized egg product

was found to be beneficial for treatment of inflammation, however, there does not appear to be any teaching that shows that the hyperimmunzied egg product somehow interferes with NSAIDs or DMARDs to reduce the effects of NSAIDs or DMARDs. Adalsteinsson suggests the use the egg product in conjunction with NSAIDs and DMARDs, but does not suggest that the egg product prevents gastrointestinal damage that may result from NSAIDs or DMARDs. Again, the two products act independently of each other.

- Applicant argues that the hyperimmune egg of Adalsteinsson provides inflammatory protection within the gastrointestinal tract. Applicant argues that there is no mention or suggestion that Adalsteinsson's hyperimmune egg crosses the gastrointestinal lining and provides a systemic effect on other areas of the body. Applicant reasons that even if glucosamine sulfate is the preferred method for treating joint inflammation in a particular subject, there would be no motivation to combine it with the hyperimmune egg of Adalsteinsson to treat joint inflammation because the egg of Adalsteinsson is not known to affect the joints.
    - In response to Applicant's arguments, it appears that the motivation relied upon by the Office is the not the same motivation relied upon by Applicant. While the motivation for arriving at the claimed invention may differ, a motivation still exists. From the Office's analysis, it would have been obvious to modify Adalsteinsson's composition of egg and NSAIDs/DMARDs with the use of glucosamine instead of NSAIDs and DMARDs. The motivation to make such a substitution comes from Yue's teachings. Yue teaches that glucosamine sulfate

has been shown to treat joint disease and suggests that it is a preferable treatment for the inflammation and pain of the joints instead of NSAIDS (col. 5, lines 19-26). Whether or not Adalsteinsson's egg product was intended to only treat inflammation within the gastrointestinal lining does not alter its actual capabilities. Adalsteinsson teaches that the hyperimmunized egg product is useful for treating arthritis, which is outside of the gastrointestinal lining. Again, it appears that Applicant's interpretation of Adalsteinsson views the hyperimmunized egg as an antidote against NSAID and DMARD effects on the gastrointestinal lining. The Office does not agree with such an interpretation and thus maintains its position with regard to the teachings of the references and motivation to combine found in Yue. Therefore, the rejection is maintained for reasons of record.

Double Patenting

The rejection of claims 46, 47 and 49-51 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-6 of U.S. Patent No. 6,706,267 B1, is maintained for reasons of record. Applicant indicates that a terminal disclaimer may be filed once allowable subject matter is indicated.

Conclusion

No claim is allowed.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stacy B. Chen whose telephone number is 571-272-0896. The examiner can normally be reached on M-F (7:00-4:30). If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Stacy B Chen 12/21/06

STACY B. CHEN
PRIMARY EXAMINER